

Remarks

The Applicant notes with appreciation the withdrawal of the 35 U.S.C. §§102 and 103 rejections based on Hind. The Applicant also notes with appreciation that the rejection of Claim 3 under 35 U.S.C. §103 over the combination of Rolf with Hind is rendered moot with the cancellation of Claim 3.

The Applicant acknowledges the sole remaining rejection in the case, namely the rejection of Claims 1 and 8 – 18 over the hypothetical combination of Rolf with Hind. The Applicant respectfully submits that all of the solicited claims are allowable inasmuch as both of Hind and Rolf teach away from the invention as recited in the solicited claims, whether they are taken individually or collectively.

The Applicant has amended independent Claims 1, 11 and 12 to further clarify differences between treating neuropathic pain and non-neuropathic pain. In particular, those claims have been amended to recite that lidocaine is topically administered to non-damaged peripheral sensory nerves near a pain locus. Support may be found throughout the Applicant's Specification such as in the text spanning paragraph [0016] on page 6 and paragraph [0018] on page 7. Thus, in this invention, lidocaine reaches the non-damaged peripheral sensory nerves at a pain locus that is typically caused by damage to the surrounding tissue. The result is analgesia produced by action on those non-damaged peripheral sensory nerves, such analgesia relieving the non-neuropathic pain caused by the damaged surrounding tissue.

This is sharply contrasted to the teachings of the prior art. In that regard, Hind attacks a totally different problem in a totally different way. Specifically, Hind is directed to the treatment of neuropathic pain that results nerve injury. It is lidocaine's direct activity on damaged neurons

that causes its pharmacologic effect. As helpfully noted by the Examiner, analgesia for such neuropathic pain may be achieved without anesthesia.

The phenomenon that Hind addresses is sharply different from this invention. Hind treats neuropathic pain by applying lidocaine to damaged peripheral sensory nerves. These peripheral sensory nerves are permanently damaged by action of herpes-zoster infection and cause pain as a consequence of such damage despite the fact that the cutaneous rash of herpes-zoster is gone. It is known that nerve damage causes an upregulation (increase) of sodium channels in the damaged nerve region, which have an abnormally high affinity for lidocaine, and thus it is believed that the lidocaine binds to these abnormally expressed sodium channels resulting in a dampening of abnormal action potentials, thereby resulting in analgesia. The Applicants attack a completely different problem in a completely different way. The Applicants treat non-neuropathic pain by applying lidocaine to non-damaged peripheral sensory nerves at a pain locus.

A consequence of what the Applicant does versus what Hind teaches is that Hind actually teaches in the opposite direction of the Applicant. Specifically, Hind attempts to treat neuropathic pain while the Applicant treats non-neuropathic pain. Hind applies lidocaine to damaged peripheral sensory nerves. The Applicant applies lidocaine to non-damaged peripheral sensory nerves. The Applicant respectfully submits that one of ordinary skill in the art simply would not look to Hind, which is directed to treatment of neuropathic pain when attempting to treat non-neuropathic pain. Those of ordinary skill in the art are well aware that the physiology of non-neuropathic pain is simply too different for the teachings of Hind to be of use when attempting to treat non-neuropathic pain. Thus, the Applicant respectfully submits that Hind is inapplicable.

The Applicant also respectfully submits that, not only does Rolf do nothing to cure the deficiencies set forth above with respect to Hind, but also leads one of ordinary skill in the art away from the invention and away from Hind. Rolf is particularly instructive at Column 5, beginning at about line 25, wherein Rolf teaches:

Any of a variety of topical medications can be used in accordance with the present invention. When the patch is used as an analgesic, these include trolamine salicylate, methyl salicylate, menthol, camphor, eucalyptus oil, spearmint oil or a combination thereof. In other applications, the medication can include anti-pruritic agents or anti-inflammatory agent such as hydrocortisone or anesthetic agents such as benzocaine or lidocaine. Also included are non-steroidal anti-inflammatory agents such as ibuprofen, especially the S-isomer of ibuprofen. Other medications include keratolytic agents such as salicylic acid, and rubefacient agents such as capsicum.

The essence of this teaching is that lidocaine should not be used to achieve analgesia, but it can be used for so-called “other” applications.

The question therefore arises as to why one of ordinary skill in the art would look to Rolf, which teaches that lidocaine should not be used for analgesia, but for “other” applications, when attempting to achieve analgesia? The answer is very simple---one of ordinary skill in the art would not look to Rolf to utilize lidocaine to achieve analgesia because Rolf teaches away from such use. If Rolf thought that lidocaine could or should be used for analgesia, he would have said so. The above text was the place to say it. Instead, Rolf teaches that lidocaine may be used for “other” applications. However, those other applications are not analgesia.

Thus, the Applicant respectfully submits that one of ordinary skill in the art would not hypothetically combine Rolf with Hind because one of ordinary skill in the art would have no incentive to do so in view of the fact that Hind attempts to provide analgesia for neuropathic pain with lidocaine, while Rolf teaches that many compounds not including lidocaine should be used for analgesia and that lidocaine should be used for “other” applications. The Applicant

respectfully submits that there is utterly no incentive to make the hypothetical combination based on such teachings. The Applicant asks the question: Why would one of ordinary skill in the art combine the use of lidocaine from Rolf for non-analgesic use to provide analgesia in Hind when Rolf says not to? One of ordinary skill in the art would not because the teachings of Rolf are clear: don't use lidocaine for analgesia.

There is a further reason why one of ordinary skill in the art would not hypothetically combine Rolf with Hind. Hind attempts to treat neuropathic pain. Rolf makes no mention at all of treating neuropathic pain. It, therefore, inherently follows that there are no teachings or suggestions that would lead one of ordinary skill in the art to believe that there could or would be a benefit to treating neuropathic pain with any of the many compounds listed by Rolf, much less lidocaine, which has not been identified as an analgesic by Rolf.

In any event, even if one of ordinary skill in the art did make the hypothetical combination, the resulting method would be quite different. Specifically, even if one of ordinary skill in the art were to directly defy the teachings of Rolf and utilize lidocaine as an analgesic in the methodology of Hind, the result would be the treatment of neuropathic pain and not non-neuropathic pain. That is not what the Applicant claims. Instead, the Applicant claims treatment of non-neuropathic pain by topically administering to non-damaged peripheral sensory nerves at a pain locus an analgesically effective amount of lidocaine. These are sharply different processes that are not related. As a consequence, even if the hypothetical combination were to be made, the resulting method would still not teach or suggest the Applicant's specifically claimed process of treating non-neuropathic pain. Withdrawal of the 35 U.S.C. §103 rejection based on the hypothetical combination of Rolf with Hind is respectfully requested.

The Applicant has added new Claim 19. It is based substantially on prior Claim 12.
Entry into the Official File and examination on the merits is respectfully requested.

In light of the foregoing, the Applicant respectfully submits that the entire Application is
now in condition for allowance, which is respectfully requested.

Respectfully submitted,



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